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AUG 2 9 2011

K103308

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

Submitter:
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Contact Person:
Crystal Dizol Hagan
Regulatory Affairs Specialist
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Date Prepared: November 8, 2010

Device Trade Name: Karl Storz AIDA HD Connect

Common Name: PACS (Picture Archiving and Communications System)

Classification Name: Picture archiving and communications system.

Regulation Number: 21 CFR 892.2050

Product Code: LLZ

Predicate Device(s):
Karl Storz: AIDA Compact II (K052159)

Device Description:
The Karl Storz AIDA HD Connect is a Windows based archiving and documentation software. The unit may include a DVD drive or Blu-Ray drive and an optional integrated SmartScreen. The unit has several types of inputs and outputs to accommodate SD and HD still image capture and video recording, audio recording, image and video display, and peripherals.

Intended Use:
The Karl Storz AIDA HD Connect is intended for use by qualified personnel in the Doctor's Office, Operating Room and Nurses Station. The Advanced Image and Data Archiving (AIDA) HD Connect is a Windows based archiving and documentation software for still images, video and audio sequences and patient data recording during a diagnostic or therapeutic procedure. It allows capture and annotation of the surgical procedure in both SD and HD for documentation purposes. Images captured and distributed by AIDA are for viewing and reference purposes and are not intended for primary diagnosis.

Technological Characteristics:
The primary difference between the Karl Storz AIDA HD Connect and the predicate device is the updating of the grabber board to perform image/video/sound capture and to provide capture in High Definition.

Non-Clinical Performance Data:
Performance testing was conducted to verify that the device meets the product requirement specifications and is fit for its intended use. Electrical safety and EMC testing were performed in accordance with IEC 60601-1 and 60601-1-2. The results of performance testing demonstrate that the characteristics of the Karl Storz AIDA HD Connect are substantially equivalent to the predicates in terms of performance.

Determination of Substantial Equivalence:
The Karl Storz AIDA HD Connect is substantially equivalent to the predicate device. As the Karl Storz AIDA HD Connect is a modified version ("update") of the predicate device, differences in performance and technology were implemented as improvements. Design control activities, including risk analysis and verification testing, demonstrate that the differences between AIDA HD Connect and the predicate do not raise any new issues of safety and effectiveness. The Karl Storz AIDA HD Connect is substantially equivalent to the unmodified predicate device as it has the same intended use and utilizes the same fundamental scientific technology to perform that intended use.

Conclusions:
The Karl Storz AIDA HD Connect is substantially equivalent to the identified predicate device and does not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Karl Storz Endoscopy-America, Inc.
% Ms. Crystal Dizol Hagan
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc
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EL SEGUNDO CA 90245-5017

AUG 29 2011

Re: K103308
Trade/Device Name: Karl Storz AIDA HD Connect
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 18, 2011
Received: August 19, 2011

Dear Ms. Hagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not yet assigned

Device Name: Karl Storz AIDA HD Connect

Indications for Use: The Karl Storz AIDA HD Connect is intended for use by qualified personnel in the Doctor's Office, Operating Room and Nurses Station. The Advanced Image and Data Archiving (AIDA) HD Connect is a Windows based archiving and documentation software for still images, video and audio sequences and patient data recording during a diagnostic or therapeutic procedure. It allows capture and annotation of the surgical procedure in both SD and HD for documentation purposes. Images captured and distributed by AIDA are for viewing and reference purposes and are not intended for primary diagnosis.

Prescription Use: ✓ AND/OR Over-The-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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